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Clinical Paper

Vaginal Hysterectomy using the ERBE BiClamp® Bipolar Vessel Sealing System: A Case Series

Gillian V Blayney¹, James P Beirne^{2,4}, Lynsey Hinds³, Declan Quinn¹, Gary J Dorman¹

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Abstract: The ERBE BiClamp® BVSS appears to be a safe and effective method of vaginal hysterectomy in this small single surgeon, single institution study; demonstrating efficient operative times, minimal blood loss and intraoperative morbidity with acceptable surgical outcomes. Its use contributes to the advancement of minimally invasive gynaecology and should be encouraged.

INTRODUCTION

Approximately 50,000 hysterectomies are performed annually in the UK¹. With fewer complications and a quicker recovery, the vaginal route is preferred over its abdominal counterpart². This is endorsed in the National Institute of Clinical Excellence (NICE) guidelines on heavy menstrual bleeding and a 34-study Cochrane review^{2,3}. The American Association of Gynecologic Laparoscopists (AAGL) highlight that hysterectomy for benign uterine disease should be performed either vaginally or laparoscopically⁴. This affirms the American College of Obstetricians and Gynaecologists' (ACOG) statement that the vaginal approach should be primary whenever feasible due to better patient outcomes and fewer complications than laparoscopic or abdominal surgery⁵. AAGL have recently launched an online master course in vaginal hysterectomy (VH) to support this⁶.

VH yields a speedier return to normal activity, fewer febrile episodes, shorter hospital admission, shorter operative time and less blood loss^{4,7}. Despite this, there is a reluctance towards VH due to the challenging surgical technique with limited access to deep vascular pedicles making haemostasis and suture ligation potentially problematic⁸. Bipolar vessel sealing systems (BVSS) are proven to be safe and efficacious with possible advantages over conventional methods, namely less post-operative pain, reduced blood loss, shorter operative time and hospital stay⁹⁻¹⁶.

The ERBE BiClamp® BVSS are insulated forceps with an automatic coagulation completion. The technique has similar anatomical principles to conventional methods, shortening the learning curve. It requires only two instruments; easing access and reducing trauma risk. Initial studies into VH using BiClamp® suggest that patients experience less post-operative pain and shorter operative duration¹⁷. Coagulation effects on innervation of the surgical field and the need for less downward traction on the uterus may explain improved post-operative pain tolerance¹⁵. These effects also prevent "back-bleeding", ensuring better haemostasis and reducing

surgical field visual impairment. We investigated the use of ERBE BiClamp® BVSS in VH in terms of safety and efficacy with possible advantages over conventional suture ligation, namely less post-operative pain, reduced blood loss, shorter operative time and hospital stay.

MATERIALS AND METHODS

The setting was a major district general hospital in Northern Ireland where a single surgeon began using the ERBE BiClamp® BVSS for VH in 2006, following a period of training with a recognised expert, Dr Henri Clavé in Nice, France.

We conducted a retrospective case review of all VH performed using the ERBE BiClamp® BVSS over a 7-year period (September 2006 – May 2014). Exclusion criteria were: VH performed by other surgeons within the same time period or using conventional suture ligation.

Details of surgical technique and device

The technique is a variation of the classical form of VH using electro-surgery via the ERBE Vio® generator and the Bi-Clamp® forceps to achieve haemostasis. Following circumferential cervical incision, the anterior and posterior pouches are carefully opened to gain access to the peritoneal cavity. The Bi-Clamp® forceps are then used to sacrifice the pelvic floor ligamentous support and the uterine vascular pedicles before being transected with curved mayo scissors.

1 Department of Obstetrics and Gynaecology, Antrim Area Hospital, Northern Health and Social Care Trust, Antrim, Northern Ireland. 2 Ovarian Cancer Research Programme, Centre for Cancer Research and Cell Biology, Queen's University, Belfast, Northern Ireland. 3 Royal-Jubilee Maternity Service, Royal Victoria Hospital, Belfast Health and Social Care Trust, Belfast, Northern Ireland. 4 Northern Ireland Centre for Gynaecological Cancer, Belfast City Hospital, Belfast Health and Social Care Trust, Belfast, Northern Ireland.

Corresponding Author: Dr GJ Dorman
gary.dorman@northerntrust.hscni.net



The salient part of the operation is the amputation of the cervix after coagulation of the uterine arteries allowing uterine rotation, not traction. This is imperative in haemostasis and negates the need for uterine prolapse. Vaginal bilateral salpingo-oophorectomy (BSO) is also possible. The vaginal vault is closed with a continuous dissolvable suture with an effort to incorporate the anterior and posterior leaves of the pelvic parietal peritoneum.

Outcome measures

Data collected included patient demographics, type of procedure and indication, including additional vaginal or laparoscopic BSO or pelvic floor repair (PFR).

Primary outcome measures included:

- Operating time: from knife to skin until closure of the vaginal vault.
- Peri-operative blood loss: determined by haemoglobin (Hb) drop between pre-operative and post-operative values (g/dL).
- Complication rate: Intraoperative, short-term, within 2 post-operative weeks and long-term complications, indicated through outpatient review and re-referral patterns.
- Post-operative analgesia requirements: determined by analgesia consumption during post-operative hospital admission, as an average dose per day.
- Length of hospital stay: in post-operative days.

RESULTS

A total of 200 patients were included over a 7 year period. (See Figure 1)

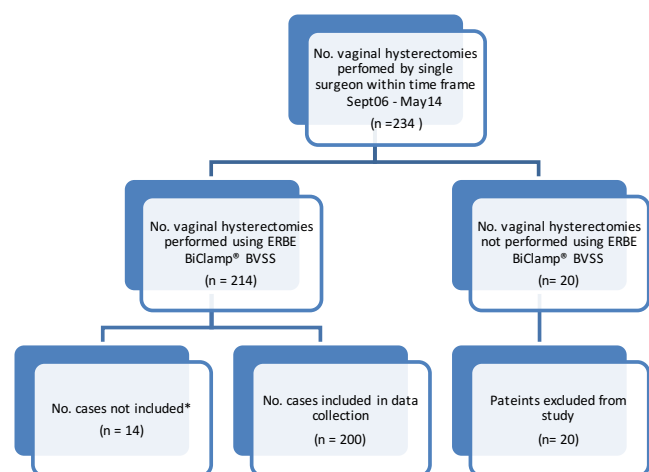


Fig 1. Formation of the study cohort

*Cases not included due to notes being unobtainable.

Median age was 51 years (range: 24–83). Median Body Mass Index (BMI) was 28.5kg/m² (Interquartile range (IQR) 9.75), based upon 60.5% of patients as this was unobtainable in the remainder. BMI was greater than 35kg/m² in 23% of patients. Regional anaesthesia only was used in 4% of cases.

Median parity was 2 (IQR 2) with 19.5% of patients being nulliparous. Obstetric history was known in 70% of patients, of whom 7% had caesarean sections. Data on previous surgery was available in 70% of patients. Of these, 50% had had no previous pelvic surgery, with the commonest previous surgery being laparoscopic sterilization (11.5%). 5% of patients had undergone a previous laparotomy. Indications for VH are detailed in Table 1. VH alone occurred in 56% of patients with 44% having additional procedures; laparoscopic BSO (28.5%), vaginal BSO (13.5%), PFR (2%). Laparoscopic BSO was only conducted if vaginal BSO was unsuccessful or not feasible.

TABLE 1:

Indications for surgery

Indication for surgery	% of patients
Benign	
Menorrhagia/failed conservative management	23.9
Cervical intra-epithelial neoplasia (CIN)	11.7
Endometriosis / Chronic Pelvic Pain	7.8
Uterovaginal Prolapse	6.3
Endometrial Hyperplasia	4.8
Other benign indications	3.4
Malignant	
Endometrial carcinoma	36.5
Cervical Carcinoma	5.3

*Other indications for surgery included prophylactic (HNPCC/BRCA carrier or family history of carcinoma), 12 week sized fibroid, previous vulval angiomyxoma.

Operating time

Median operating time for VH (+/- BSO or PFR) was 47 minutes (IQR 9, Mean 49.72+/-15.07, 95% CI 47.21-52.23). 83% of VH alone were <60 minutes. Median operating time for VH and Laparoscopic BSO was 75 minutes (IQR 27, Mean 75.65+/-20.31, 95% CI 70.16-80.14). 64% of all operations were <60 minutes. Operating time was not recorded in 2% of cases.

Peri-operative blood loss

Median Hb drop was 1.2g/dL (IQR 0.9, Mean 1.128+/-0.833, 95% CI 0.952-1.305), based upon 44% of patients as 48.5% did not have a post-operative Hb measurement and in 7.5% results were unobtainable.

Complications

93% of cases had no major intraoperative complications. The commonest complication was bladder injury (2.5%), but this wasn't associated with long term sequelae. In 2 cases, this was not due the BiClamp® forceps and occurred during dissection of the anterior fornix. There were no incidents of



bowel injury, labial or vaginal burns. Additional haemostatic sutures to pedicles were required in 4.5% of operations. Abdominal/laparoscopic conversion rate was 2%, due to bleeding with no subsequent long term complications. 2% of patients underwent conversion to laparotomy, all of whom had a BMI >35kg/m². Indications for conversion to laparotomy included bleeding (1.5%) and poor laparoscopic views (0.5%). In one case, ureteric injury resulted in anuria and acute nephropathy due to bilateral distal ureteric kinking with partial obstruction, secondary to vaginal vault closure. This necessitated ureteric stenting (which was removed six months following surgery) and bilateral nephrostomies. After follow-up, the patient was discharged with no long term complications. An American Society of Anaesthesiologists (ASA) physical status classification of >1 occurred in 65% of patients (of the 70% in which ASA was recorded), highlighting the extent of co-morbidity within our population. Consequently, in this high-risk group, anaesthetic problems, namely atrial fibrillation, asystole, which recovered, and chest pain occurred in 1.5% of cases.

Return to theatre occurred in 2.5%, indications being; bleeding, haematoma evacuation and ureteric injury. Vault haematoma occurred in 2.5% of patients with 1% returning to theatre. Two patients required transfusion of packed red blood cells, in accordance with UK Blood Transfusion Advisory Committee Guidelines¹⁸. Both patients returned to theatre on the first post-operative day due to bleeding. Urinary retention requiring an indwelling catheter on hospital discharge occurred in 2% of patients, none of whom experienced voiding dysfunction beyond 2 post-operative weeks. Direct microscopy-confirmed urinary tract infection (UTI) rate was 4%. Hospital readmission occurred in 2% of patients, indications being urosepsis, vault haematoma, post-operative ileus, and constipation. There were no recorded cases of venous thromboembolism or death related to surgery.

Long term follow up was conducted through telephone calls, outpatient review or re-referral and involved physical examination if warranted. 4% of patients were lost to follow up and duration ranged from 6 months-5 years. There were no long-term complications reported in 97% of cases. Prolapse requiring further surgery occurred in 1% of cases and persistent pelvic pain in 2% of cases, 50% of which pelvic pain and endometriosis were the initial indication for surgery.

Post-operative analgesia requirements

Simple analgesia was required by 76.5% of patients (Paracetamol, Codeine Phosphate or Non-steroidal anti-inflammatories). The average number of doses per day of Paracetamol (1g) or Codeine Phosphate (60mg) was 2.58 and of non-steroidal anti-inflammatory drugs (Sodium Diclofenac 75mg) was 0.8. 2.5% of patients received Tramadol and one patient received hyoscine butylbromide.

Opioid analgesia consumption occurred in 23.5% of patients, at an average of 0.98 doses per day (range 0.14–3.75) (1 dose = 5mg Morphine Sulphate). A patient-controlled analgesia

system was used by 2% of patients, 75% of whom underwent conversion to laparotomy returned to theatre.

Length of hospital stay

37% of patients were discharged on the first post-operative day and 89% were discharged within 3 days. Median length of stay was 2 days (IQR 2, Mean 2.13+/-1.34, 95% CI 1.94–2.32). 79.5% of patients were admitted the night before surgery, to ensure bed availability, however length of hospital stay was measured in post-operative days. 10.5% of patients were admitted on the day of surgery and discharged on the first post-operative day.

DISCUSSION

This retrospective case review suggests that ERBE BiClamp® BVSS is a safe and effective alternative to its conventional counterpart in VH. Intraoperative morbidity was minimal, 83% of VH alone were less than 60 minutes, median haemoglobin drop was 1.2g/dL, post-operative stay was 2 days and 76.5% of patients required simple analgesia only. The commonest intraoperative complication was bladder injury (2.5%), resulting in no long-term morbidity. Bleeding requiring laparotomy/laparoscopy and conversion to laparotomy both occurred in 2% of patients. UTI was the commonest short-term complication (4%). 97% of patients reported no long term complications.

This study of BiClamp® BVSS is, to our knowledge, the largest conducted by a single surgeon, in a single institution. We note an improvement in operator performance with time, with only one intraoperative complication (conversion to laparotomy due to bleeding and difficult access in a patient with a BMI of 47kg/m²) occurring in the last 16 months of data collection. One strength of our study is that high BMI wasn't an exclusion criterion, with 23% of patients having a known BMI >35kg/m². Intraoperative complication rate in patients with BMI <35kg/m² compared to BMI >35kg/m² was 5.4% and 11% respectively. This result is limited as BMI data was obtained for only 60.5% of the cohort. Caesarean section also wasn't a contra-indication, with 7% of patients having had at least one previous caesarean. This did not increase the intraoperative complication rate.

Our study was a retrospective, single surgeon, single institution study so it is difficult to know how this will translate into wider clinical practice. Data collection was based on review of medical records and may not have been complete. Peri-operative blood loss data, for example, was based upon 44% of the cohort, mainly because post-operative Hb measurements are not routine. In our institution, intraoperative surgical protocol dictates that all patients have a pre-operative Hb measurement. If this is low or estimated blood loss is significant, a post-operative Hb is measured. Prospective data collection would allow blood loss estimation through counting and weighing of surgical swabs. Furthermore, weight and size of uterine specimens was unobtainable. Secondly, post-operative pain was determined by analgesia consumption, however prospective

data collection may have permitted the use of pain intensity scores. Thirdly, as a control group was not included, this study is not a direct comparison to conventional methods of VH. A prospective randomised control trial (RCT) however, would allow for direct comparison. Our results have therefore, been compared with other published evidence, as detailed below.

A recent meta-analysis, incorporating eight RCTs, on electrosurgical bipolar vessel sealing (EBVS) for VH included 772 patients, with 2 studies, pooling 118 cases, reporting BiClamp® usage^{19,21}. Main outcomes included operative duration, intraoperative blood loss, complication rate and hospital stay¹⁹. We report similar results to those outlined. A shorter operating time with EBVS over suture ligation is reported by all studies. Estimated blood loss in our study wasn't comparable as blood loss wasn't calculated in millilitres, however Pergialiotis et al. conclude that the mean difference in blood loss between EBVS and suture ligation was statistically significant ($p < 0.001$)¹⁹. Ghirardini et al. report similar findings to our results with ΔHb of 1.4g/dl in their 500-case BiClamp® VH study²². They also present similar results regarding surgery duration (mean 48.9 minutes) and hospital stay (mean 3.2 days)²².

We report an intraoperative complication rate of 3% (6/200) which, whilst not statistically significant, is less than conventional suture ligation (OR = 0.5216 (95% CI – 0.1987-1.3693) $p = 0.1863$ $Z = 1.322$) and better than the meta-analysis EBVS / suture ligation comparison (OR = 0.9560 (95% CI – 0.452-2.0222) $p = 0.9063$ $Z = 0.118$). (See Figure 2)¹⁹ Similar findings are noted in the individual intra-operative complication rates with our data approaching statistical significance and displaying better P values than the EBVS/suture ligation comparison. (See Figure 3) Specifically, our rate is lower than the BiClamp® VH subgroup (3.3%, 1/30) and is over six times the size²⁰. We report no labial burns and one case of ureteric injury, a complication not recorded in the meta-analysis.

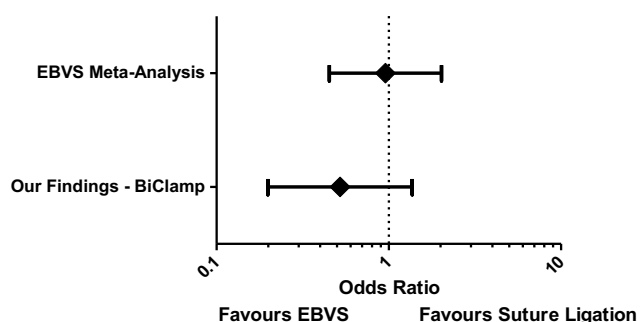


Fig 2. Intraoperative complications forest plot: our findings in comparison to the meta-analysis. (Data from Pergialiotis et al. 2014)²⁰

A 19.2% major post-operative complication rate, which is lower than the meta-analysis suture ligation is close to statistical significance (OR = 0.3697 (95% CI – 0.1226-1.1151) $p = 0.0773$ $Z = 1.767$). This is again less than both EBVS and suture ligation (OR = 0.5863 (95% CI – 0.2643-1.3009) $p = 0.1892$ $Z = 1.313$). (See Figures 4 and 5)

Pergialiotis et al. conclude that EBVS systems, in comparison to traditional suture ligation, lead to a statistically significant decrease in intraoperative blood loss but don't shorten operative duration or influence complication rate¹⁹. It is however, important to note that interpretation is limited by small numbers of BiClamp® VH.

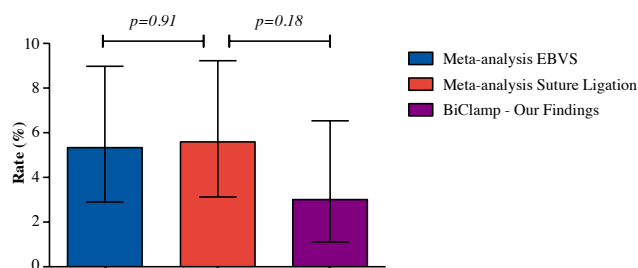


Fig 3. Intraoperative complication rates of each group in comparison (Data from Pergialiotis et al. 2014)²⁰ EBVS: 5.364 (2.933-9) Suture Ligation: 5.597 (3.133-9.231) BiClamp: 3 (1.101-6.53) EBVS v Suture $p = 0.91$ BiClamp vs Suture $p = 0.18$

We conclude that VH using BiClamp® does not compromise patient safety. Safe surgical technique is paramount, particularly in electro surgery, and can be promoted through training. The technique closely mimics classical VH, making the learning curve achievable. It is a safe, effective, easier alternative to conventional suture ligation; particularly in the absence of uterine descent or a narrow vaginal introitus. Notably, 19.5% of our patients were nulliparous and BMI was $>35\text{kg/m}^2$ in 23%. The Northern Ireland population is very stable and highly amenable to follow up, facilitating close monitoring for long-term complications for up to seven years.

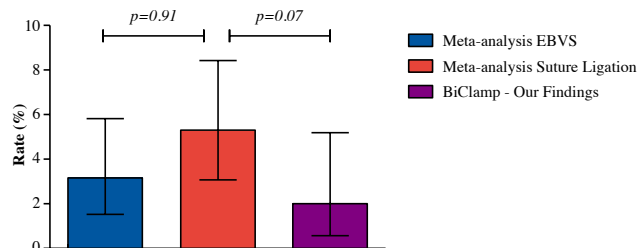


Fig 4. Major post-operative complications each group in comparison. (Data from Pergialiotis et al. 2014)²⁰ EBVS: 3.135 (1.503-5.765) Suture: 5.231 (3.047-8.375) BiClamp: 2 (0.545-5.14) EBVS v Suture $p = 0.19$ BiClamp vs Suture $p = 0.07$

CONCLUSION

This study, to our knowledge, is the largest conducted in a single institution by a single surgeon. It suggests that ERBE BiClamp® BVSS as a safe, effective alternative to conventional suture ligation in VH, compared with previously published outcomes. The technique affords quicker operative times, less blood loss, minimal intraoperative morbidity and acceptable surgical outcomes. The reduced post-operative pain observed confers more rapid mobilisation and improved recovery. A prospective RCT would be recommended.

Modern medical practice demands clinicians to consider minimally invasive surgical options which are, at the very



least, equal to their conventional counterparts. Our results suggest BiClamp® can achieve this. The procedure closely mimics the classical performance of VH, reducing the learning curve in mastering the technique and allowing the general gynaecologist to perform VH with improved ease and safety. BiClamp® BVSS appears to be an ideal platform to allow the replacement of the trans-abdominal route of hysterectomy with the preferred minimally invasive vaginal approach.

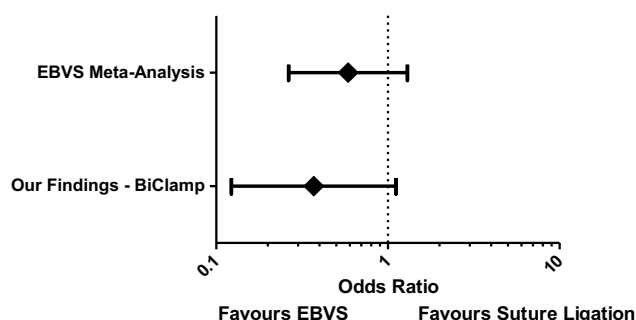


Fig 5. Major post-operative forest plot: our findings in comparison to the meta-analysis. (Data from Pergialiotis et al. 2014)²⁰

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Ethical Approval: As this project was solely an audit of intra- and post-operative outcomes for the purposes of service evaluation it was not deemed necessary to submit to the Regional Ethics Committee for approval.

Statistics: Statistics analysis was completed using MedCalc Statistical Software version 16.8.4 (MedCalc Software bvba, Ostend, Belgium; <https://www.medcalc.org>; 2016) and the graphs was devised using GraphPad Prism v5.00 www.graphpad.com GraphPad Software INC. CA, USA.

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